UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AZURITY PHARMACEUTICALS, INC.	:	
Plaintiff,	:	
v.	:	CIVIL NO. 1:20-CV-10280-RWZ
EDGE PHARMA, LLC	:	
Defendant.	:	

EDGE'S MEMORANDUM OF LAW TO SUBMIT ADDITIONAL AUTHORITY IN FURTHER SUPPORT OF EDGE'S MOTION TO DISMISS AND IN FURTHER OPPOSITION TO AZURITY'S MOTION FOR PRELIMINARY INJUNCTION

TABLE OF CONTENTS

PAGE

TABLE OF AUTHORITIES

Page(s)

Federal Cases

Rules

Defendant Edge Pharma, LLC ("Edge") submits this Memorandum of Law to submit additional authority in further support of its motion to dismiss (Dkt. Nos. 20-22) and in further opposition to the preliminary injunction motion of Azurity Pharmaceuticals, Inc. ("Azurity") (Dkt. Nos. 2-3, 24-26).

PRELIMINARY STATEMENT

The Central District of California recently issued highly-relevant and persuasive decisions in *Nexus Pharmaceuticals, Inc. v. Leiters, Inc.*, Case No. 2:20-cv-07328 (C.D. Cal. Oct. 29, 2020) and *Nexus Pharmaceuticals, Inc. v. Quva Pharma, Inc.*, 2020 WL 6498970 (C.D. Cal. Oct. 29, 2020). The court in those cases dismissed all of the plaintiff's unfair competition and consumer protection claims, which were based on alleged violations of the "essentially a copy" provision of Section 503B of the Food, Drug, and Cosmetics Act (the "FDCA")—the very provision at issue here. The court held that such claims were impliedly preempted by the FDCA. As discussed further below, the court's decisions support Edge's arguments that: (1) Azurity's claims are precluded because their adjudication would usurp the FDA's policymaking authority; (2) Azurity's claims are barred by the doctrine of primary jurisdiction; and (3) Azurity's state law claim under Chapter 93A is preempted by the FDCA.

Moreover, the court in *Leiters* and *Quva Pharma* relied on a ***declaration from the FDA***, which cautioned against judicial interpretation of the "essentially a copy" provision of Section 503B with respect to a compounding process that uses an FDA-approved product as a starter—again, the very circumstances at issue here. Edge uses an FDA-approved drug product in its vancomycin compounding process. The FDA's declaration also confirmed: (1) that the agency has never pursued an enforcement action on these facts; and (2) that the agency intends to issue ***new clarifying guidance on this issue in the near future***.

As Edge explained in its earlier-filed briefs (Dkt. Nos. 22, 24, 37, 42), the case law compels dismissal of Azurity's claims. The FDA itself has now cautioned that lawsuits just like this one—private efforts to "enforce" the "essentially a copy" provision of Section 503B—can threaten the objective of consistent regulatory interpretation.

BACKGROUND

Azurity alleges that Edge's compounded vancomycin product violates Section 503B of the FDCA in two respects: (1) Edge is purportedly compounding its vancomycin product using a "bulk drug substance" that does not appear on the "503B Bulks List"; and (2) Edge's vancomycin product is "essentially a copy" of Azurity's FDA-approved drug, which is branded as FIRVANQ. Compl. ¶¶ 22-23, 43-51. But as noted in Edge's prior filings, Edge no longer uses a "bulk drug substance" to compound its vancomycin product. Edge uses an FDA-approved drug product as a starter. Dkt. No. 25 (Chatoff Decl. ¶ 20 & Ex. 3 at 12); *see also* Dkt No. 24 at 15. Azurity's "bulk drug substance" claim is meritless and moot.

Because it has no private right of action under the FDCA (*see POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014)), Azurity seeks to convert its FDCA allegations into a Lanham Act and Chapter 93A case. Azurity contends that Edge violated Section 43(a) of the Lanham Act because Edge violated Section 503B of the FDCA. Compl. ¶¶ 60-63. Azurity presents the following syllogism: Edge markets itself as an approved 503B outsourcing facility that complies with FDA rules; Edge allegedly does not comply with these rules with respect to vancomycin production; therefore, Edge is engaged in false advertising and promotion. Compl. ¶¶ 84-90. This syllogism is flawed and fails as set forth below.

Edge has moved to dismiss Azurity's Lanham Act and Chapter 93A claims on three common grounds: (1) Azurity fails to allege false statements of fact by Edge (*i.e.*, Edge's purported misstatements are not actionable) (Dkt. No. 20 at 7-15); (2) Azurity's claims are precluded because their adjudication would usurp the FDA's policymaking authority (Dkt. No. 20 at 15-18); and (3) Azurity's claims are barred by the doctrine of primary jurisdiction (Dkt. No. 20 at 18-19) . Edge also argues that Azurity's Chapter 93A claim is preempted by the FDCA. Dkt. No. 20 at 19-20 (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001)).

THE NEW AUTHORITY

I. THE DECISIONS IN *LEITERS* AND *QUVA PHARMA*

On October 29, 2020, the United States District Court for the Central District of California ruled on Rule 12(b)(6) motions to dismiss in *Nexus Pharmaceuticals, Inc. v. Leiters, Inc.*, Case No. 2:20-cv-07328 (C.D. Cal. Oct. 29, 2020) (Dkt. 70) and *Nexus Pharmaceuticals, Inc. v. Quva Pharma, Inc.*, 2020 WL 6498970 (C.D. Cal. Oct. 29, 2020). *See* Declaration of Robert J. Fluskey Jr., dated November 24, 2020 ("11.24.20 Fluskey Decl."), Ex. 1 (*Leiters*) & Ex. 2 (*Quva Pharma*).

The plaintiff in both cases—Nexus Pharmaceuticals—alleged that the defendants violated Section 503B of the FDCA by compounding drugs that were "essentially a copy" of Nexus's FDA approved drugs. *Id.* Ex. 1 at 4; Ex 2 at *2. Like Azurity, Nexus was not able to pursue a private right of action under the FDCA, so it presented its FDCA allegations under the guise of "unfair competition." In *Leiters,* Nexus asserted claims under California's Unfair Competition Law, Florida's Deceptive and Unfair Trade Practices Act, and Colorado's Consumer Protection

Act. *Id.* Ex. 1 at 1-2. In *Quva Pharma*, the plaintiff asserted claims under California's Unfair Competition Law, Florida's Deceptive and Unfair Trade Practices Act, and Texas's Unfair Competition Laws. *Id.* Ex 2 at *1.

The court dismissed all of Nexus's claims based on implied FDCA preemption. The court explained that the plaintiff's claims exist only because of the FDCA's requirements, which "the FDA has the exclusive authority to enforce." *Id.* Ex. 1 at 6-7; Ex. 2 at *3. The court, quoting the *Imprimis* decision relied upon by Edge (Dkt. No. 37 at 3) and Azurity, held that "***whether Defendant's product is 'essentially a copy' of Nexus's product is a determination which 'implicates various exceptions that 'directly implicate the FDA's rulemaking authority.***'" *Id.* Ex. 1 at 7 (quoting *Allergan USA Inc. v. Imprimis Pharms., Inc.*, 2017 WL 10526121, at *8 n.1 (C.D. Cal. Nov. 14, 2017)) (emphasis added); Ex. 2 at *3. The court further held that the "***determination of whether Defendants' product is 'essentially a copy' of Nexus's . . . product, in violation of the FDCA, must be left to the FDA***." *Id.* Ex. 1 at 8 (emphasis added); Ex. 2 at *4 (emphasis added).

II. The FDA Declaration and Press Release Announcing Upcoming Guidance on "Essentially a Copy"

The court in *Leiters* and *Quva Pharma* relied, in part, on a declaration submitted by the FDA's Acting Director of the Division of Compounded Drugs, Maria Edisa Gozun. *Id.* Ex. 1 at 7-8; Ex. 2 at *4. In that declaration, Ms. Gozun confirmed that the FDA has "not taken any compliance or enforcement action . . . in which FDA relied on the 'essentially a copy' provisions set forth in Section 503B of the FDCA with respect to outsourcing facilities that compound drug products using FDA-approved drug products—rather than bulk drug substances—as a starting point." *Id.* Ex. 3 (Gozun Declaration) ¶ 8 (cited and quoted in Ex. 1 at 8 & Ex. 2 at *4).

Ms. Gozun also stated that the FDA intends to clarify and revise its guidance relating to the application of the "essentially a copy" test:

> FDA publicly announced on September 10, 2020, that it has received questions and comments related to its policies for applying the 503B 'essentially a copy' provisions when outsourcing facilities compound drugs starting with an FDA-approved drug product rather than a bulk drug substance. FDA plans to address these comments in an upcoming revision to its guidance for outsourcing facilities.

Id. Ex. 3 ¶ 9 (cited and quoted in Ex. 1 at 8 & Ex. 2 at *4). The September 2020 FDA press release referenced by Ms. Gozun is attached as Exhibit 4 to the 11.25.20 Fluskey Declaration. The Court may take judicial notice of this press release. *See, e.g., Gustaven v. Alcon Labs., Inc.*, 272 F. Supp. 3d 241, 252 (D. Mass. 2017); Fed. R. Evid. 201.

Notably, in authorizing Ms. Gozun's declaration, the FDA emphasized that her testimony was critical to ensure consistent interpretation of FDA guidance:

> FDA has determined that authorizing the requested testimony would be in the public interest and promote the objectives of the FDCA and the agency . . . ***FDA believes that the requested testimony furthers the objectives of the FDCA and the agency as it relates to an action where a private party seeks to enforce provisions of the FDCA that have not served as the basis for an FDA enforcement action and may require further FDA interpretation. The agency has publically announced that it is planning to address questions and comments related to its policies for applying the 'essentially a copy' provisions when outsourcing facilities compound drugs starting with FDA-approved drug products in a forthcoming revision to its guidance for outsourcing facilities.*** Accordingly, FDA believes that the requested testimony is in the public interest because it would discourage an interpretation of the relevant provisions that could be potentially inconsistent with FDA's interpretation and future enforcement actions.

11.25.20 Fluskey Decl. Ex. 3 at Ex. B (FDA letter) (emphasis added).

The *Leiters* and *Quva Pharma* court recognized that ensuring consistency in the interpretation of FDA regulations and guidance was a principal objective of judicial deference: "The FDA authorized Ms. Guzman's testimony because it 'would be in the public interest and promote the objectives of the FDCA and the agency . . . because it would discourage an interpretation of the relevant provisions that could be inconsistent with FDA's interpretation and future enforcement actions.'" *Id.* Ex. 1 at 7-8; Ex. 2 at *4.

THE NEW AUTHORITY'S RELEVANCE

The decisions in *Leiters* and *Quva Pharma*, the Gozun declaration, and the FDA's September 2020 press release announcing new agency guidance all support dismissal of Azurity's case and denial of Azurity's preliminary injunction motion. Azurity, just like Nexus, is suing because Edge's conduct allegedly violates the FDCA. Azurity's claims exist only because of the FDCA's requirements of Section 503B, which the FDA has the exclusive authority to enforce.

As reinforced by the decisions and FDA statements cited above, Azurity's case is an improper effort to pursue a private right of action under the FDCA. The preclusion, primary jurisdiction, and preemption doctrines are especially important here because ruling on the "essentially a copy" provision of Section 503B would require the Court to opine on unsettled subject matter and exercise discretionary policy judgments for the FDA. *See* Dkt. No. 22 at 16-20; Dkt. No. 24 at 11-13. The Central District of California ***and the FDA*** have effectively confirmed Edge's arguments and concerns. Indeed, the FDA has announced its intention to publish new guidance on the exact FDCA claim at issue here—namely, application of the "essentially a copy" provision to compounded drugs manufactured with an FDA-approved starter.

This Court should reject Azurity's invitation to intervene in the FDA's unsettled and incomplete policymaking process. Azurity's claims are barred by the doctrines of preclusion, primary jurisdiction, and preemption.

November 24, 2020

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CERTIFICATE OF SERVICE

I, William J. Egan, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on November 24, 2020.

/s/ William J. Egan
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